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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,243	06/15/2001	Nils Carlin	CARL3003/REF	7055

23364 7590 05/18/2004

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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,243	CARLIN ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5-39* is/are pending in the application.

4a) Of the above claim(s) *13-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 5-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *102303*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Request for Continued Examination

1) A request for continued examination under 37 C.F.R 1.114, including the fee set forth in 37 C.F.R 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R 1.114, and the fee set forth in 37 C.F.R 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R 1.114. Applicants' submission filed on 10/27/03 has been entered.

Applicants' Amendment

2) Acknowledgment is made of Applicants' amendment filed 10/27/03.

Election

3) Acknowledgment is made of Applicants' election filed 2/2/04, without traverse, in response to the written lack of unity mailed 01/21/04. Applicants have elected invention I, claims 1 and 5-39.

Status of Claims

4) Claims 2-4 have been canceled via the amendment filed 10/23/03.

New claims 5-39 have been added via the amendment filed 10/23/03.

Claims 1 and 5-39 are pending.

Claims 13-39 have been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Elected claims 1 and 5-12 are under examination.

Information Disclosure Statement

5) Acknowledgment is made of Applicants' Information Disclosure Statement filed 10/23/03. The information referred to therein has been considered and a signed copy of the same is attached to this Office Action.

Prior Citation of Title 35 Sections

6) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

7) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) under 35 U.S.C. § 112, First Paragraph

8) Claims 1 and 5-12 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 includes the negative limitations: 'does not contain heat stable enterotoxin (ST)'. However, there is no descriptive support in the specification, as originally filed, for this negative limitation". Therefore, the above-identified negative limitations in claim 1 are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification, as filed, for the above-identified limitation(s), or to remove the new matter from the claim(s).

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

9) Claims 1 and 5-12 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is redundant in the recitation: '*E. coli* bacteria'. Since one of skill in the art would readily understand the *E. coli* are 'bacteria', it is suggested that Applicants delete the recitation 'bacteria' (see line 4).

(b) Claims 5-7 are redundant in the recitation: '*E. coli* ..... bacterial strain'. Since one of skill in the art would readily understand the recites *E. coli* strain is a 'bacterial' strain, it is suggested that Applicants delete the recitation 'bacterial'.

(c) Claims 6 and 7 lack a period at the end of each claim. The claims also lack a comma at the end of each subsection, i.e., (i), (ii) and (iii).

(d) Claim 6 is grammatically incorrect in the limitation: 'vaccine comprise' (see line 1). To obviate the rejection, it is suggested that Applicants replace the limitation with --vaccine comprises--.

(e) Claims 6 and 7 are inconsistent with other dependent claims, such as, claims 2 and 8-12 in the limitation: 'The vaccine according to claim ....'. For clarity and consistency, it is suggested that Applicants replace the limitation with --The oral vaccine according to claim .....--.

(f) Claims 5-12, which depend directly or indirectly form claim 1, are also rejected as being indefinite due to the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

10) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11) Claims 1 and 5-12 are rejected under 35 U.S.C § 102(b) as being anticipated by Savarino *et al.* (*J. Infect. Dis.* 177: 796-799, March 1998 – Applicants' IDS) as evidenced by Holmgren *et al.* (WO 92/14487).

The reference of Savarino *et al.* qualifies as prior art under 35 U.S.C § 102(b) since instant claims are not granted priority to 12/18/1998 due to the lack of descriptive support for the negative imitation in claim 1: 'does not contain heat stable enterotoxin (ST)'.

Savarino *et al.* disclosed an oral ETEC/rCTB vaccine produced by SBL Vaccin, Stockholm comprising formalin-inactivated ETEC SBL101 expressing CFA/I; SBL104 expressing CS4+CS6; SBL105 expressing CS5+CS6; SBL106 expressing CS1; and SBL 107 expressing

CS2+CS3 mixed with 1.0 mg of rCTB, wherein ST is removed (see page 796; and Materials and Methods). Although Savarino *et al.* is silent about the exact amounts of the various CS or CFA antigens in the vaccine, the prior art vaccine is viewed as the same as the Applicants' vaccine for the following reason(s). Since the prior art ETEC SBL101 expressing CFA/I; SBL104 expressing CS4+CS6; SBL105 expressing CS5+CS6; SBL106 expressing CS1; and SBL 107 expressing CS2+CS3 are structurally the same as the ones recited in the instant claims, they are expected to produce or contain the same amount of the various CFA or CS antigens. The Office's position that the prior art vaccine is the same as the Applicants' vaccine is based upon the fact that every specific *E. coli* strain present in the prior art oral vaccine and Applicants' vaccine are the same. In spite of the fact that Savarino *et al.* are silent about the amounts of CFA or CS antigens in their vaccine, there is sufficient strain identity to reasonably conclude that the prior art vaccine is one and the same as the Applicants' vaccine. Since the prior art ETEC SBL101 expressing CFA/I; SBL104 expressing CS4+CS6; SBL105 expressing CS5+CS6; SBL106 expressing CS1; and SBL 107 expressing CS2+CS3 are structurally the same as the ones recited in the instant claims, they are expected to contain or produce the same amount of the various CFA or CS antigens. Since the Office does not have the facilities for examining and comparing Applicants' ETEC strains with that of the prior art ETEC strains for quantities of CFA/CS antigens produced or contained therein, the burden is on the Applicants to show a novel or an unobvious difference between the instantly claimed vaccine and the prior art vaccine, i.e., to show that the prior art vaccine does not possess the same material and functional characteristics of the instantly recited vaccine. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzerald et al.*, 05 USPQ 594. Further, that the prior art oral ETEC/rCTB vaccine produced by SBL Vaccin is intrinsically contained in buffered saline is inherent from the teachings of Savarino *et al.* in light of what was known in the art at the time. For instance, Holmgren *et al.* disclosed that SBL ETEC/rCTB vaccine contained or was administered in a buffered solution (see Example 5).

The teachings of Savarino *et al.* anticipate the instant claims. Holmgren *et al.* is **not** used as a secondary reference in combination with Savarino *et al.*, but rather is used to show that every

element of the claimed subject matter is disclosed by Savarino *et al.*('003) with the unrecited limitation(s) being inherent in view of what is known in the art as explained above. See *In re Samour* 197 USPQ 1 (CCPA 1978).

Claims 1 and 5-12 are anticipated by Savarino *et al.*

Relevant Prior Art

12) The prior art made of record and not relied upon in any of the rejections is considered pertinent to Applicants' disclosure:

- Holmgren *et al.* (US 6,558,678) disclosed a method of producing an ETEC vaccine consisting of formalin-killed SBL 101, SBL 102 and SBL 103 strains combined with CTB (see Example 5 and claims).

Remarks

13) Claims 1 and 5-12 stand rejected.

14) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the USPTO Fax Center which receives papers 24 hours a day and seven days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

15) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

S. DEVI, PH.D.
PRIMARY EXAMINER

May, 2004